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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,218	10/24/2005	Katsuya Okumura	279585US0XPCT	8263

22850 7590 07/03/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
07/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/554,218	OKUMURA ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6 and 8-46* is/are pending in the application.

4a) Of the above claim(s) *32-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6 and 8-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed March 11, 2008. Claims 1 and 13 were amended. Claims 2, 3 and 7 were cancelled. Applicant's amendment requiring a filter having a thickness of 2 to 7 micrometer necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

2. Claims 1, 4-6 and 8-46 are pending in this application.

3. Claims 32-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention of group II and III there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 15, 2007.

4. Claims 1, 4-6 and 8-31 are under examination.

Amendments to Claims

5. Amendments to the claims 1 and 13 have been reviewed and entered.

Claim Rejections - 35 USC § Second Paragraph

5. All rejections set forth in the previous office action regarding claim 13 have been withdrawn in view of claim amendments.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1, 4-6, 8-11 and 22-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Haushalter (WO 02/094846 published Nov. 28, 2002) further evidenced by Kubota (USPGPUB NO. 2003/0111416, filed Jan. 17, 2001).

Regarding claim 1, Haushalter teaches a microarray apparatus that includes substrate (Fig. 4A, # 12), with side walls (Fig. 4A, # 36), thus teaching a well. Haushalter also teaches that the porous region (Fig. 4A, # 14) comprises a mesh (Fig. 4A, # 34) with a plurality of pores extending there through (Fig. 4A, # 35, pg. 20, lines 15-18), thus teaching that the mesh comprises straight pores. The mesh of the Haushalter is the filter of the claim. Haushalter further teaches that the mesh region is in the recessed area of the substrate, i.e., well, (pg. 20, lines 18-21 and 29-32), which meets the limitation of a filter at the bottom of the well.

Haushalter also teaches that pores are uniform (Fig. 4D) and have a diameter ranging from about 10 nm to about 1 mm depending on the intended use of the apparatus (pg. 18, lines 16-24) and arranged at uniform spacing (Fig. 1, pores # 14). Haushalter explicitly teaches that the porous region comprising the mesh has a thickness of 1 to 1000 microns (pg 23, lines 9-10), which encompass the claimed range of filter thickness of 2 to 7 microns. Haushalter also teaches a support element on the

lower side of the filter in the well to provide mechanical support to the filter (Fig. 4A, # 20, pg. 17, lines 3-5, pg. 20, lines 15-17) and is the reinforcing rib part of the claim.

Haushalter also teaches that the porous regions on the surface is in the range of about 1 to about 10 and about 10 to about 100 per cm2 (pg. 18, lines, 26-33) and further teaches that the pores of the porous regions on the substrate have a diameter ranging between about 0.1 millimeter in diameter and about 1 millimeter diameter. Haushalter also teaches that the size of the individual pores as well as overall size of the porous region and density of the porous regions on the substrate is varied depending on the intended use of the apparatus (pg. 18, lines 22-24). Furthermore, teachings of Haushalter encompass 50 porous region per cm2 of pore diameter of 1 mm, which occupies an area of 50 mm2 square area (pg. 18, lines 15-32), which is an open area ratio of 50%, which is within the range of 15 to 60% as claimed.

Open area ratio is defined in the art as Open area ratio (%) = 100x (area of pore section)/ (area of pore section) + (area of non-pore section), as evidenced by Kubota et al (paragraph 0029). It is noted that the reference of Kubota et al is used only to confirm known fact about open area ratio in the art.

Haushalter also teaches that the apparatus comprising nucleic acid oligomers in the porous region is used for detecting nucleic acids in a sample (pg. 32, lines 20-34), thus teaching that the apparatus of Haushalter is a biochip.

Regarding claim 4, Haushalter teaches a microarray apparatus, wherein the surface of the filter is formed of silica (pg. 21, lines 20-23).

Regarding claim 5, Haushalter teaches a microarray apparatus that includes a plurality of wells provided integrally with each other (See Fig. 3A, a plurality of wells # 14, pg. 18, lines 29-33).

Regarding claim 6, Haushalter teaches a microarray apparatus that also contains many single wells (Fig. 4A # 14).

Regarding claim 8, Haushalter teaches that the support element is provided as a mechanical support to the substrate (i.e., reinforcing rib), comprising porous region with a plurality of through-holes (Fig. 2, Supporting element # 20, through holes # 14). Haushalter also teaches that the support element and the substrate (Fig, 2, # 12) coupled together by seal and functions as single substrate/support component (pg. 17, lines 30-32), thus teaching the reinforcing rib part is of integral type.

Regarding claim 9, Haushalter teaches that the support element is joined to the mesh (i.e., filter) is joined directly to filter by a seal (Fig. 4A, supporting element # 20, Seal, # 24, pg. 18, lines 4-13).

Regarding claim 10, Haushalter teaches that the supporting element (i.e., reinforcing rib) and the substrate comprising filter are formed of silicon wafers (pg. 17, lines 25-27), thus teaching rib and the filter being formed of an identical material. Haushalter also teaches that reinforcing rib part is joined directly to filter by a seal so as to continually extend from the filter (Fig. 4A, supporting element # 20, Seal, # 24, pg. 18, lines 4-13).

Regarding claim 11, Haushalter teaches a microarray apparatus wherein support underneath the wall, a nonporous part free from pores of filter is provided on the bottom

of the well in a predetermined width from the periphery of well (Fig. 4A, Wall # 36, See the structure underneath the wall).

Regarding claim 22, Haushalter teaches a microarray apparatus that includes a holder, i.e., a vessel to support substrate comprising a plurality porous region formed integrally with each other (Fig. 2, vessel # 26, porous regions # 14, pg. 16, lines 29-31). Haushalter further teaches that the porous region is in the recessed area of the substrate, i.e., well, (pg. 20, lines 18-21 and 29-32). Haushalter also teaches that the apparatus comprising nucleic acid oligomers in the porous region is used for detecting nucleic acids in a sample (pg. 32, lines 20-34), thus teaching that the apparatus of Haushalter is a biochip. Since Haushalter teaches both vessel and a biochip, it is a biochip kit as described in the instant specification (Instant specification paragraph 0291).

Regarding claim 23, Haushalter teaches a microarray apparatus that includes a holder, i.e., a vessel integrated with wells via assembly (Fig. 2, # 26, pg. 16, lines 29-31).

Regarding claim 24, Haushalter teaches a biochip kit which is assembled with the holder (Compare Fig. 1 vs. Fig. 2, # 26, pg. 16, lines 29-31), thus teaching holder, i.e., vessel is formed independently of biochip wells.

Regarding claim 25, Haushalter teaches that the microarray apparatus includes a holder, i.e., a vessel (Fig. 6A, # 44) with compartments (Fig. 6A, # 48a) corresponding to the well on the porous region (Fig. 6A, # 46a, pg. 24, lines 4-16). The compartment in the vessel of Haushalter is broadly interpreted as well.

Regarding claim 26, Haushalter teaches that the vessel contains compartment comprising through hole in a tube on bottom side of the compartment (Fig. 6B, tube # 56, pg. 25, lines 17-24).

Regarding claim 27, Haushalter teaches that microarray apparatus wherein the substrate comprising porous region (Fig. 6A, # 47) and the holder (Fig. 6A, # 44) are connected to each other so that corresponding wells are connected to each other.

Regarding claim 28, Haushalter teaches a biochip kit wherein substrate (Fig. 1, # 12, back support (Fig. 1, # 20), seal (Fig. 1, # 24) and a holder (Fig. 1, # 26) are stacked on top of each other and further teaches seal and back support plates have a through hole and holder plate is free from through holes (Fig. 1).

Regarding claim 29, H Haushalter teaches that the microarray apparatus includes a holder, i.e., a vessel (Fig. 6A, # 44) with compartments (Fig. 6A, # 48a) corresponding to the well on the porous region (Fig. 6A, # 46a, pg. 24, lines 4-16). The compartment in the vessel of Haushalter is broadly interpreted as well. Haushalter also teaches that porous regions in the apparatus contain a plurality of compounds including nucleic acids, peptides, drugs, protein (pg. 30, lines 30-34, pg. 33, lines 4-10), thus teaching a plurality of biochips. Since each porous region of Haushalter corresponds to each compartment (i.e., well) in the holder, teachings of Haushalter encompass a plurality of biochips, which are connected to each other so that the corresponding wells are connected to each other.

Regarding claim 30, Haushalter teaches a biochip kit wherein the flat part of the lower chamber, i.e., a vessel well provided on the lower end of the well side part of biochip (Fig. 6A, # 44). Haushalter also teaches that flat part of the upper substrate, i.e., upper end of the well side is connected to each other via assembly (Fig. 6A, # 47, pg. 24, lines 4-16).

Regarding claim 31, Haushalter teaches a biochip kit wherein the upper end of the biochip well is assembled with wells of the vessel using the O- ring (Fig. 6A, # 50 and # 52, wells 48a, 48b) which has convex and concave part, thus teaching a positioning concave part into which a convex part provided on the upper end of the well side of the biochip to the lower end of the well side of the vessel part in separate compartments (Fig. 6A-D, pg. 25, lines 4-34). Each compartment above and below the tube in Fig. 6A, is broadly interpreted as separate vessel.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haushalter (WO 02/094846 published Nov. 28, 2002) further evidenced by Kubota (USPGPUB NO. 2003/0111416, filed Jan. 17, 2001) in view of Chafin et al (USPGPUB NO. US 2003/0109031 published June 12, 2003).

Claim 12 is dependent from claim 1. Teachings of Haushalter regarding claim 1 are described in this office action in section 8.

Regarding claim 12, Haushalter teaches a microarray apparatus that includes a filter at the bottom of the well (Fig. 4 # 14) but is silent about the filter on top of the well so that wells are sandwiched between the two filters. However, filter on top of the well was known in the art before the invention was made as taught by Chafin et al who teaches a device for detecting target in a sample that includes a filter between pretreatment chamber and the first chamber (Fig. 3C, filter # 118, pretreatment chamber # 114, first chamber # 122, paragraph 0041-0042). Chaffin et al further teaches that the pretreatment chamber is for lysing cells and the first chamber is for collecting partially purified nucleic acids for detecting the target on a detection card (paragraph 0039-0042). Chaffin also teaches the filter is used to collect samples and for removing cellular debris for direct analysis of target in the samples (paragraphs 0042-0045).

The combined teachings of Haushalter and Chafin et al, thus provides two filters one on the top of the well to collect sample without any cellular debris and directly using the sample to identify the target with the filter at the bottom of the well thus sandwiching the well between two filters.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the filter of Chafin et al in the device of Haushalter with the expected benefit of collecting the samples and for removing cellular debris for direct analysis of the target in the sample as taught by Chaffin et al (paragraphs 0042-0045).

11. Claims 1 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haushalter (WO 02/094846 published Nov. 28, 2002) further evidenced by Kubota (USPGPUB NO. 2003/0111416, filed Jan. 17, 2001) in view of Weiner et al (USPGPUB NO. US 2003/0096268 published May 22, 2003).

Teachings of Haushalter regarding claim 1 are described in this office action in section 8.

Regarding claim 13-21, Haushalter teaches probes in the well (pg. 31, lines 21-30), but is silent about probe-supported particles and their dimension. However, probe supported particles and their dimension was known in the art at the time of the claimed invention was made as taught by Weiner et al.

Weiner et al teaches a DNA detection and sequencing apparatus that includes micro reactor vessels, i.e., wells having at its bottom an inorganic membrane filter with

0.2 micron channels, i.e., pores (Fig. 2, paragraph 0069) and further teaches that the filter is from Whatman PLC sold under the brand name Anopore, which has parallel micro channels and a thickness of 60 micrometer (paragraph 0069), which is a straight pore filter with a uniform diameter arranged at uniform pore spacing. Weiner et al also teaches that the wells are supported by side walls on the upper side of the well. Weiner et al also teaches apparatus is a DNA sequencing apparatus (paragraph 0058), thus teaching a biochip.

Regarding claim 13, Weiner et al teaches that the apparatus include micro reactor vessels with solid support (i.e., particles) immobilized with nucleic acids probes dispersed therein in wells (Fig. 2, paragraphs 0030 and 0058).

Regarding claim 14, Weiner teaches an embodiment wherein the beads are 40 micron and the membrane pore diameter is of 30 micron and the ratio between the diameter of bead particles and the pore diameter is 1.333, which is within the range of 1.1 to 2.5 as claimed (paragraph 0174). It is noted that the particle size relative to pore spacing has less bearing on the patentability of the claim.

Regarding claim 15, Weiner teaches an embodiment wherein the beads are 40 micron and the membrane pore diameter is of 30 micron, thus teaching the ratio between the diameter of particles and the pore diameter is 1.333, which is in the range of 1.1 to 2.5 as claimed (paragraph 0174). Weiner does not teach the relationship between, particle size and pore diameter and pore spacing to meet the limitation of the formula.

However, In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (MPEP 2144.04).

Weiner teaches that the pressure difference across the CMRA wells is prevented by introducing fluid via multiple inlets to maintain uniform flow in each wells (paragraph 0112) and therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the particle size and pore diameter and pore spacing as an alternative means to maintain the uniform flow in all the wells.

Regarding claim 16, Weiner et al teaches beads conjugated with nucleic acid sequence, i.e., probe-supported particles and is the identification means for providing probe identification information (Example 1, paragraph 0170).

Regarding claim 17, Weiner et al teaches that the well contains 10 million beads and each bead has 3 million copies of nucleic acid probes (paragraphs 0170-0171 and 0174) and the gene sequence is the identification means of the probe-supported particle (Example 1, paragraph 0170).

Regarding claim 18, Weiner et al teaches that well contains 10 million beads and each bead has 3 million copies of same nucleic acid probes (Example 1, paragraphs 0170-0171 and 0174), thus teaching a plurality of probe-supported particles which are

identical to each other in nucleic acid sequence, thus plurality of probe supported particles have identical information.

Regarding claim 19, Weiner et al teaches that well contains 10 million beads and each bead has 3 million copies of same nucleic acid probes (Example 1, paragraphs 0170-0171 and 0174), but contain A, G, C and T nucleotides and therefore probe identification information are different from each other in said probe identification information for a plurality of probe-supported particles contained therein.

Regarding claim 20, Weiner teaches an embodiment wherein the reagent immobilized on the mobile solid support, i.e., particles have are different polypeptides with different enzyme activity thus teaching a plurality of probe-supported particles are different from each other in probe identification information by enzyme activity identification means are contained in an identical well (paragraph 0064). Weiner et al also teaches that wells are identical to each other in construction of probe identification information in all the identification means for a plurality of probe-supported particles contained therein (paragraph 0164).

Regarding claim 21, Weiner teaches an embodiment wherein the reagent immobilized on the solid support, i.e., particles have different polypeptides with different enzyme activity and further teaches that polypeptide is a fusion protein with both luciferase and sulfurylase activity (paragraph 0164). Weiner also teaches that beads are coupled with either luciferase polypeptide or sulfurylase polypeptide having their own individual activity (paragraph 0164) thus teaching a plurality of probe-supported particles are different from each other in their enzymatic activity, which is the probe

identification information means (paragraph 0164). Teaching of Weiner et al of enzymatic activity as an identification means meets the limitation of at least one identification means for a plurality of probe-supported particles contained therein (paragraph 0164). Teachings of Weiner et al of different beads having different enzymatic activity also meets the limitation of wells are different from each other in construction of probe identification means as exemplified by luciferease being different from sulfurylase.

Weiner et al teaches that the beads have very high binding capacity for probe binding (paragraphs 0170-0171).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the probe supported particles of Weiner et al in the device of Haushalter with a reasonable expectation of success.

One with the ordinary skill in the art at the time of the claimed invention was made would have included the probe supported particles of Weiner et al in the device of Haushalter with the expected benefit of having a probe supported particles with a very high binding capacity as taught by Weiner et al (paragraphs 0170-171).

Response to remarks from the Applicants

Claim rejections under 35 U.S.C. § 102(b)

12. Applicant's arguments have been considered but are moot in view of the new grounds of rejection necessitated by claim amendments (Remarks pgs. 14-15).

Claim rejections under 35 U.S.C. § 103(a)

13. Applicant's arguments have been considered but are moot in view of the new grounds of rejection necessitated by claim amendments (Remarks pgs. 15-16).

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, AU 1634

Narayan K. Bhat, Ph. D.

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Primary Examiner, Art Unit 1634